REMARKS

Claims 1-2, 6-26, 29-42, 44-47, 49, 52-54, and 59-76 remain in this application. Claims 1, 4, 17, 23, 36, 42, 44, 52, 56 have been amended. New claims 59-76 have been added. Claims 3, 27-28, 43, 48, 55 and 58 were previously canceled. Claims 4, 5, 50-51, and 56-57 are hereby canceled without prejudice or waiver of the right to pursue the subject matter of said claims in this or another application. All other claims remain the same. Reconsideration of the claims as presented in requested.

New claims 59, 62, 65, 68, 71 and 75 specify, "the composition possesses a disintegration time of 9 to 90 seconds according to USP <701>". Applicants submit that no new subject matter has been added by way of this amendment. Support for this subject matter is found in the original specification as filed (pg. 34, lines 13-17; Example 4 at pg. 35, line 14; Example 5 at pg. 36, line 14; Example 6 at pg. 37, line 14; Example 7 at pg. 38, line 14; Example 8 at pg. 39, line 14; and Example 9 at pg. 40, line 15).

New claims 60, 63, 66, 69 and 72 specify, "the one or more surfactants is present, the one or more glidants is present, the one or more fillers is present, and the one or more lubricants is present". Applicants submit that no new subject matter has been added by way of this amendment. Support for this subject matter is found in original claims 1, 23, 36, 44 and 52 (each claim optionally requires each of the specified elements) and the specification as filed (Examples 4-9; each including each of the specified components).

New claims 61, 64, 67, 70 and 73 specify, "ethylcellulose and optionally lactose". Applicants submit that no new subject matter has been added by way of this amendment. Support for this subject matter is found in original specification as filed (tables in Examples 7-9, which exemplify tablet further comprising ethylcellulose or ethylcellulose and lactose).

New claim 74 specifies a rapidly dissolving solid oral compressed composition. It defines the magnesium salt as granular MgO, a combination of hydrophilic polymers (PEG and poloxamer), crospovidone; one or more surfactants; one or more glidants; ethylcellulose; optionally lactose; one or more lubricants; a substantially anhydrous process; the solubility of the magnesium salt; the absence of microcrystalline cellulose; and the presence of the magnesium salt as the only component present in a therapeutically effective amount. Applicants submit that

no new subject matter has been added by way of amendment. Support for the added subject matter is found in original claim 52 and the specification as set forth above.

New claim 76 specifies, "the polyethylene glycol is polyethylene glycol having a molecular weight of 3000-8000, and the poloxamer is poloxamer 188". Applicants submit that no new subject matter has been added by way of amendment. Support for the added subject matter is found in original the specification as filed (Examples 4-9; pg. 10, lines 14-17).

Claims 17 and 42 stand objected to due to a typographical error. Applicants have amended the claims to replace the term "taper" with the term –tamper- as requested by Examiner. Applicants submit that this rejection has been overcome.

Claims 1-2, 4-26, 29-42, 44-47, 49-54 and 56-57 stand rejected under 35 U.S.C. 112, 1st Para. for failing to comply with the written description. Examiner has requested removal of the proviso excluding erythritol. Applicants have amended the claims as requested. Applicants respectfully submit that this rejection has been overcome and request that it be withdrawn.

Claims 1-2, 4-26, 29-42, 44-47, 49-54 and 56-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Luber et al. (US 2003/0068373). Examiner argues that Luber et al. disclose immediate release tablets containing an active agent, such as magnesium salt (magnesium hydroxide, magnesium carbonate or magnesium hydroxide), a powdered wax, lubricant, glidant, surfactant, disintegrant. Examiner also relies upon the "excellent disintegration time" disclosed by Luber et al. (Para. [0015]). Insofar as it may apply to the present claims, this rejection is traversed.

Claims 1, 23, 36, 44, and 52 were amended to specify "a combination the hydrophilic of polymers polyethylene glycol and poloxamer" and to remove the proviso excluding erythritol. The claims were also amended to specify "one or more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate". The support for the added subject matter is found in original claims 4, 5, 50, 51, 56 and 57 and the specification as filed (Examples 4-9; pg. 23, line 3; pg. 21, line 7; pg. 11, lines 7-9; and pg. 11, lines 4-7; pg. 25, line 2). Moreover, the preamble of the claims was amended to replace the term "comprising" with the term -consisting essentially of- and to specify

a "rapidly disintegrating and rapidly dissolving" composition or dosage form. Support for the added subject matter is found in the specification as filed (pg. 1, lines 3-4; pg. 9, lines 14-19).

Applicants note that there is a substantial and meaningful difference between the disintegration of a tablet and the dissolution of a tablet and its ingredients. Applicants note that the USP specification for rapid release tablet of MgO is as set forth in the instant specification, "USP 27/NF 22 specification for magnesium oxide tablets (not for tablets containing another drug) is not less than 75% (Q) of the labeled amount of MgO is dissolved in 45 minutes." (pg. 34, lines 5-12). The USP 27/NF 22 specification is based upon the USP <711> test for dissolution of the active ingredient, not for disintegration of a tablet. On the other hand, USP <701> is a test based upon disintegration of a tablet (pg. 34, lines 13-17).

Applicants respectfully submit that Luber et al.'s use of, and therefore Examiner's understanding of, the terms "dissolution" and "disintegration" is not clear. Luber et al. refer to "rapidly disintegrating tablets, stating, "Although the wax is hydrophobic, the tablet has excellent disintegration." (Abstract) They also refer to tablets with excellent dissolution and excellent disintegration, stating, "Although the powdered wax is hydrophobic, the tablets have excellent disintegration, and meet the USP dissolution specifications for immediate release tablets containing the active ingredient." (Para. [0009])

However, the corresponding Patent No. 7,323,192 more clearly specifies the function and purpose of the invention as set forth in claim 1 which reads as follows.

> 1. A swallowable immediate release tablet consisting essentially of at least 60 weight % of acetaminophen, from about 1 to about 10 weight % of a powdered wax having an melting point greater than about 90°C and a particle size in the range of about 5 to about 100 microns, and less than about 25 weight % of a disintegrant, wherein the acetaminophen is released from the swallowable immediate release tablet by 30 minutes in pH 5.8 buffer.

Clearly, Luber et al. are indicating that disintegration (due to release) and not dissolution is what is occurring by 30 minutes in pH 5.8 buffer. Moreover, the file history of USSN 09/966,493, which underlies the Luber et al. patent, includes various clarifying statements made by Luber et al. In the amendment filed June 28, 2004, Luber et al. specifically and vehemently differentiate (pgs. 5-11 of the amendment) between disintegration and dissolution when distinguishing their claimed invention over the disclosure of Remon (WO 01/21155 A1). Luber

et al. indicate that their invention is directed to rapid dissolution which they correlate to release of the active agent. In the amendment filed April 18, 2007, Luber et al. again argue (pg. 7) the importance of dissolution and its correlation to release and indicate that their tablets provide about 100% dissolution of acetaminophen in about 15 min. In that same amendment, Luber et al. then distinguish their claimed invention over Remon by stating, "However, it is not seen where Remon disclose or even suggests the desirability of a **swallowable immediate release tablet.** [emphasis added] In fact, it is respectfully submitted that Remon teaches away from a **swallowable** [emphasis added] tablet, including an immediate release swallowable tablet." (pg. 16)

Accordingly, the disclosure of Luber et al. is directed to tablets that have a disintegration time that approximates the dissolution time of the acetaminophen. This is because the tablet of Luber et al. must be swallowable. This means that both disintegration and dissolution occurs after swallowing by a subject, and the tablets of Luber et al. cannot disintegrate prior to swallowing by a subject. Luber et al. disclose rapidly "dissolving" tablets that dissolve within 15 or 30 minutes after exposure to USP dissolution conditions (see examples); and, none of the exemplary tablets of Luber et al. contain MgO. In other words, the tablets of Luber et al. appear to take 15 to 30 min to dissolve under USP conditions. The tablets of Luber et al. require at least 60% wt of active ingredient, up to 20% wt of a wax, and not more than 25% wt of other ingredients (Paras. [0012], [0015], [0016], [0018]). Luber et al. specifically state, "The direct compression process enables the minimization or elimination of water-soluble, non-saccharide polymeric binders such as polyvinyl pyrrolidone, alginates, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose, and the like, which can have an adverse effect on dissolution." (Para. [0021]). In other words, use of a water soluble, non-saccharide polymeric binder will necessarily cause an increase in dissolution time rather than a decrease in dissolution time.

Applicants have discovered, however, that the water-soluble, non-saccharide polymeric binders do not have "an adverse effect on dissolution". In fact, the instant rapidly dissolving dosage forms and compositions specifically require a combination of polyethylene glycol and poloxamer, a copolymer that is not even contemplated by Luber et al. The combination of hydrophilic polymers PEG and poloxamer together with one or more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose

sodium, and sodium starch glycolate, and the exclusion of microcrystalline cellulose, render the instant compositions capable of a "substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system".

Moreover, the instant tablets are capable of "a disintegration time of 9 to 90 seconds according to USP <701>" (see new claims 59, 62, 65, 68, 71 and 75). None of the dosage forms of Luber et al. are able to achieve such fast disintegration rates. As noted above, each of the dissolution tables of Luber et al. specify minimal dissolution times of 15 minutes or 30 minutes, with no mention as to the disintegration time thereof but with the requirement that the tablets must be swallowable and with arguments on record indicating that their invention is not a swallowable suspension. In fact, Luber et al. specifically teach away from such a rapid dissolution time to ensure that their tablets are swallowable, as noted above.

Accordingly, Luber et al. fails to teach or suggest a rapidly dissolving and rapidly disintegrating solid oral composition as claimed. Applicants respectfully submit that this rejection has been overcome and request that it be withdrawn.

Applicants respectfully submit that new claims 59-76, each of which specifies "a disintegration time of 9 to 90 seconds according to USP <701>", are patentable over Luber et al., which discloses dissolution times of 15 min to 30 min and which inherently requires, by virture of the statements of Luber et al., a disintegration time that approximates the dissolution time of the tablets. The instant rapid disintegration and dissolution times are made possible by the combination of elements included within the instant claims.

Applicants respectfully submit that new claims 61, 64, 67, and 70, each of which specifies "ethylcellulose and optionally lactose", are patentable over Luber et al., which does not disclose or suggest tablets consisting essentially of polyethylene glycol, poloxamer, ethyl cellulose, optionally lactose and possessing the other elements recited in the parent claims.

Applicants respectfully submit that claim 76 is patentable over Luber et al., which first of all does not even contemplate poloxamer and in particular does not contemplate a particular grade of poloxamer, nor does it contemplate a particular grade of polyethylene glycol.

Applicants have made a diligent effort to advance prosecution of the instant application by presenting claim amendments and supportive argumentation. Applicants respectfully submit

that the invention as claimed is allowable over the art of record. An early notice of allowance thereof is requested.

Respectfully submitted,

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